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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/749,025	12/27/2000	Petrus Johannes Maria Nuijten	99511 US	6121

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EXAMINER
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ART UNIT	PAPER NUMBER
1645	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/749,025	NUIJTEN ET AL.	
	Examiner	Art Unit	
	Vanessa L. Ford	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 April 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *7,10,11,19-22,24,28-32,34 and 36-40* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *7,10,11,19-22,24, 28-32, 34 and 36-40* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *03 January 2002* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on April 20, 2007 has been entered. Applicant's declaration filed under 1.132 submitted by Dr. Nuijten is acknowledged. Claim under examination are 7, 10-11, 19-22, 24, 28-32, 34 and 36-40.

2. Applicant's Declaration filed under 1.132 is acknowledged and is sufficient to overcome the rejections under 35 U.S.C. 112, first paragraph.

Rejection Withdrawn

3. In view Applicant's amendment and remarks the following rejections are withdrawn:

a) rejection of claims 22, 24, 28-29 and 31-32 under 35 U.S.C. 112 first paragraph, pages 2-11 of the Final Office action is withdrawn.

b) rejection of claim 37 under U.S.C. 112 second paragraph, page 20, paragraph 8.

4. The rejection under 35 U.S.C. 102(b) as anticipated by Joys et al is maintained for claim 7 for the reasons set forth on pages 11-14, paragraph 4 of the previous Office Action.

The rejection is reiterated below:

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Joys et al teach compositions comprising fla- (non-flagellate) *Salmonella typhimurium* bacterium in broth culture (page 48-49). Broth culture is a pharmaceutically acceptable carrier because the instant specification teaches that "such a carrier may be as simple as water, but e.g. also comprise culture fluid in which the bacteria were cultured (page 12). Claim limitations such as "an improved *Salmonella* vaccine" and "an improvement in a marker vaccine" are being viewed as limitations of intended use. It should be remembered that a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. The claimed limitation "wherein the marker vaccine is in a freeze-dried or sprayed –dried form is being viewed as a process limitation. Joys et al anticipate the claimed invention.

Since the Office does not have the facilities for examining and comparing applicant's composition with the composition of the prior art, the burden is on the applicant to show a novel or unobvious difference between the claimed product and the product of the prior art (i.e., that the composition of the prior art does not possess the same material structural and functional characteristics of the claimed composition). See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

Applicant's Arguments

A. Applicant urges that Joys et al fails to disclose an immunologically effective amount of a live mutated bacteria that are *Salmonella enterica* that in their wild type form carried flagella having at least one antigenic determinant.

B. Applicant urges that freeze-drying the Salmonella bacterial cultures as suggested by the Office action would change the principle operations of Joys et al.

Examiner's Response to Applicant's Arguments

Applicant's arguments filed April 20, 2007 have been fully considered but they are not persuasive.

A. The claims are drawn to an immunogenic composition comprising a live mutated bacterium and a pharmaceutically acceptable carrier wherein the live mutated *Salmonella enterica* in their wild-type form carried flagella having at least one antigenic determinant and wherein after the mutation the live mutated bacteria are not capable of inducing an immune response to at least one antigenic determinant of flagellin.

Joys et al teach live *Salmonella typhimurium* bacterium in broth culture (page 48-49). Broth culture is a pharmaceutically acceptable carrier because the instant specification teaches that "such a carrier may be as simple as water, but e.g. also comprise culture fluid in which the bacteria were cultured (page 12 of instant specification). Joys et al teach that the mutated bacterium are non-flagellated (fla- mutants). Therefore, these mutants are not capable of inducing an immune response to at least one antigenic determinant of flagellin.

B. To address Applicant's comments regarding the product being freeze-dried", claim 11 has been removed from this rejection.

In view of the all of the above this rejection is maintained.

5. The rejection under 35 U.S.C. 102(b) as anticipated by Lockman et al is maintained for claim 7 for the reasons set forth on pages 14-17, paragraph 5 of the previous Office Action.

Lockman et al teach compositions comprising fla- (non-flagellate, lacks at least one antigenic determinant of flagellin) *Salmonella typhimurium* bacterium in broth culture containing glucose (page 139). Broth culture is a pharmaceutically acceptable carrier because the instant specification teaches that "such a carrier may be as simple as water, but e.g. also comprise culture fluid in which the bacteria were cultured (instant specification, page 12). Claim limitations such as "an improved *Salmonella* vaccine" and "an improvement in a marker vaccine" are being viewed as limitations of intended use. It should be remembered that a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. The claimed limitation "wherein the marker vaccine is in a freeze-dried or sprayed – dried form is being viewed as a process limitation. Lockman et al anticipate the claimed invention.

Since the Office does not have the facilities for examining and comparing applicant's composition with the composition of the prior art, the burden is on the applicant to show a novel or unobvious difference between the claimed product and the product of the prior art (i.e., that the composition of the prior art does not possess the same material structural and functional characteristics of the claimed composition). See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

Applicant's Arguments

A. Applicant urges that Lockman et al fails to disclose an immunologically effective amount of a live mutated bacteria that are *Salmonella enterica* that in their wild type form carried flagella having at least one antigenic determinant. Applicant urges

that the mutated bacterium of Lockman et al are not immunogenic because they did not confer immunity.

B. Applicant urges that Lockman et al teach away from an "immunogenic composition".

Examiner's Response to Applicant's Amendments

A. The claims are drawn to an immunogenic composition comprising a live mutated bacterium and a pharmaceutically acceptable carrier wherein the live mutated *Salmonella enterica* in their wild-type form carried flagella having at least one antigenic determinant and wherein after the mutation the live mutated bacteria are not capable of inducing an immune response to at least one antigenic determinant of flagellin.

Lockman et al teach live *Salmonella typhimurium* bacterium in broth culture containing glucose (page 139). Broth culture is a pharmaceutically acceptable carrier because the instant specification teaches that "such a carrier may be as simple as water, but e.g. also comprise culture fluid in which the bacteria were cultured (page 12 of instant specification). Lockman et al teach that the mutated bacterium are non-flagellated (fla- mutants). Therefore, these mutants are not capable of inducing an immune response to at least one antigenic determinant of flagellin.

B. To address Applicant's comments regarding Lockman et al teaching away from "immunogenic compositions" because the composition containing the fla- mutants did not confer immunity, it should be remembered that an immunogenic antigen is not

required to induce an "protective" immune response, it is only required to produce an "immune response". The fla- strains produced an immune response but not a response as high as the fla+ strains. See page 137 of Lockman et al. Thus, Lockman et al does not teach away from immunogenic compositions.

In view of the all of the above this rejection is maintained.

6. The rejection under 35 U.S.C. 102(b) as anticipated by Wahdan et al is maintained for claims 19, 22, 24, 28, 29, 30, 32 and 34 for the reasons set forth on pages 17-18, paragraph 6 of the previous Office Action.

Wahdan et al teach a vaccine comprising a nonmotile of *Salmonella typhi* Ty2 (TNM1)(see the Abstract and the Title). Wahdan et al teach that the TNM1 was acetone-killed and lyophilized (page 69). Wahdan et al teach that the TNM1 vaccine is identical to other *S. typhi* whole cell vaccines prepared with Ty2 except that it is devoid of the H antigen (lacks at least one antigenic determinant of flagellin) (page 71). Wahdan et al teach that the vaccines were reconstituted the morning of the day it was to be used (page 70). Thus, water is necessarily in the vaccine compositions. Claim limitations such as "an improved *Salmonella* vaccine" and "an improvement in a marker vaccine" are being viewed as limitations of intended use. It should be remembered that a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. Wahdan et al anticipate the claimed invention.

Since the Office does not have the facilities for examining and comparing applicant's composition with the composition of the prior art, the burden is on the applicant to show a novel or unobvious difference between the claimed product and the product of the prior art (i.e., that the composition of the prior art does not possess the same material structural and functional characteristics of the claimed composition). See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

Applicant's Arguments

Applicant urges that Wahdan et al fails to disclose an immunologically effective amount of an inactivated mutant wherein the inactivated mutant having a mutation in a gene encoding flagellin.

Examiner's Response to Applicant's Arguments

Wahdan et al teach a vaccine comprising a nonmotile *Salmonella typhi* Ty2 (TNM1). Wahdan et al teach a mutant that has a mutation in the gene encoding flagellin because Wahdan et al teach a mutant devoid of the flagellar antigens (see the Abstract). Therefore, these mutants are not capable of inducing an immune response to at least one antigenic determinant of flagellin. It should be noted that the mutants of Wahdan et al were *acetone-killed (*inactivated) (page 3324). Wahdan et al teach that the nonmotile Salmonella *typhi* Ty2 (TNM1) was administered with tetanus toxoid (an adjuvant).

In view of the all of the above this rejection is maintained.

7. The rejection under 35 U.S.C. 102(b) as anticipated by Anderson is maintained for claims 19, 22, 24, 28, 30 and 34 for the reasons set forth on pages 18-19, paragraph 8 of the previous Office Action.

Anderson teaches stable non-motile strains of *Salmonella typhi* and *Salmonella paratyphi* (A and B) which are devoid of flagella (lacks at least one antigenic determinant of flagellin) capable of producing the TH, AH or BH antibodies (page 1). Anderson teaches that the *Salmonella* organisms used in the vaccine compositions are heat-killed, alcohol-killed or acetone-killed (page 2). Anderson teaches that the vaccine compositions of the invention can be freeze-dried cultures (page 2). Claim limitations

such as "an improved *Salmonella* vaccine" and "an improvement in a marker vaccine" are being viewed as limitations of intended use. It should be remembered that a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. Anderson anticipates the claimed invention.

Since the Office does not have the facilities for examining and comparing applicant's composition with the composition of the prior art, the burden is on the applicant to show a novel or unobvious difference between the claimed product and the product of the prior art (i.e., that the composition of the prior art does not possess the same material structural and functional characteristics of the claimed composition). See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

Applicant's Arguments

Applicant urges that Anderson fails to disclose an immunologically effective amount of an inactivated mutant wherein the inactivated mutant having a mutation in a gene encoding flagellin.

Examiner's Response to Applicant's Arguments

Anderson teaches a vaccine comprising a nonmotile mutant of *Salmonella typhi* or paratyphi A or B (page 1). Anderson teaches a mutant that has a mutation in the a gene encoding flagellin because Anderson teaches a mutant devoid of the flagellar antigens (page 1). Therefore, these mutants are not capable of inducing an immune response to at least one antigenic determinant of flagellin. It should be noted that the mutants Anderson teaches were inactivated by heat, acetone, phenol or alcohol (page 2). Anderson et al teach that the vaccine composition of the invention are freeze-dried (page 2).

In view of the all of the above this rejection is maintained.

8. The rejection under 35 U.S.C. 103(a) as unpatentable over Anderson in view of Cox et al is maintained for claims 19, 22, 24, 28, 29-30, 32 and 34 for the reasons set forth on pages 20-22, paragraph 9 of the previous Office Action.

The rejection is reiterated below:

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Anderson teaches stable non-motile strains of *Salmonella typhi* and *Salmonella paratyphi* (A and B) which are devoid of flagella (lacks at least one antigenic determinant of flagellin) capable of producing the TH, AH or BH antibodies (page 1). Anderson teaches that the *Salmonella* organisms used in the vaccine compositions are heat-killed, alcohol-killed or acetone-killed (page 2). Anderson teaches that the vaccine compositions of the invention can be freeze-dried cultures (page 2).

Anderson teach do not teach the use of adjuvants.

Cox et al teach adjuvants have been used to improve vaccine efficacy since the 1920s (p. 248, 1st paragraph). Cox et al teach that alum is a aluminum salt that has been used in human and veterinary vaccines since 1930 and has an excellent safety record (p. 250, 2nd column, 4th paragraph). Cox et al also teach that cholera toxin is a bacterial toxin and has been proposed as a possible human adjuvant (p. 253, 1st column, 3rd paragraph).

It would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to use adjuvants in the immunological compositions and vaccine compositions because Cox et al teach that adjuvants have been used to improve vaccine efficacy since the 1920s (p. 248, 1st paragraph).

Applicant's Arguments

Applicant urges that Anderson fails to disclose an immunologically effective amount of an inactivated mutant wherein the inactivated mutant having a mutation in a gene encoding flagellin.

Anderson teaches a vaccine comprising a nonmotile mutant of *Salmonella typhi* or paratyphi A or B (page 1). Anderson teaches a mutant that has a mutation in the a gene encoding flagellin because Anderson teaches a mutant devoid of the flagellar antigens (page 1). Therefore, these mutants are not capable of inducing an immune response to at least one antigenic determinant of flagellin. It should be noted that the mutants Anderson teaches were inactivated by heat, acetone,.phenol or alcohol (page 2). Anderson et al teach that the vaccine composition of the invention are freeze-dried (page 2). Anderson does not teach the use of adjuvants. However, Cox et al teach that adjuvants have been used to improve vaccine efficacy since the 1920s. One with ordinary skill would be motivated to add an adjuvant to the composition as taught by Anderson because Cox et al teach that adjuvants have been used to improve vaccine efficacy since the 1920s. It should be point out that Applicant did not argue the Cox et al reference.

In view of all of the above this rejection is maintained.

9. The rejection under 35 U.S.C. 103(a) as unpatentable over Hackett et al in view of Cox et al is maintained for claims 7, 10, 11, 20, 29, 31-32 and 37-40 for the reasons set forth on pages 22-23, paragraph 10 of the Final Office Action.

The rejection is reiterated below:

Hackett et al teach vaccine composition comprising flagella negative (fla-) strains of live *Salmonella* bacteria (see the Abstract). Hackett et al teach that were constructed by mutating the fla gene (pages 78-79). Hackett et al teach that the vaccine composition were delivered NaCl (page 82).

Hackett et al do not teach the use of adjuvants.

Cox et al teach adjuvants have been used to improve vaccine efficacy since the 1920s (p. 248, 1st paragraph). Cox et al teach that alum is a aluminum salt that has been used in human and veterinary vaccines since 1930 and has an excellent safety record (p. 250, 2nd column, 4th paragraph). Cox et al also teach that cholera toxin is a bacterial toxin and has been proposed as a possible human adjuvant (p. 253, 1st column, 3rd paragraph). It would be obvious to freeze-dry the compositions of Hackett et al since Hackett et al teach that lyophilized strains were used to produce both the fla- and fla+strains.

It would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to use adjuvants in the immunological compositions and vaccine compositions because Cox et al teach that adjuvants have been used to improve vaccine efficacy since the 1920s (p. 248, 1st paragraph).

Applicant's Arguments

Applicant urges that Hackett et al do not each the claim limitations " an immunologically effective amount of live mutated bacteria" and "wherein after mutation, said live mutated bacteria are not capable of inducing an immune response to at least one antigenic determinant of flagellin.

Applicant urges that Hackett in view of Cox et al to teach all recited claim limitations.

Examiner's Response to Applicant's Arguments

Hackett et al teach vaccine composition comprising flagella negative (fla-) strains of live *Salmonella* bacteria (see the Abstract). Hackett et al teach that were constructed by mutating the fla gene (pages 78-79). Hackett et al teach that the vaccine composition were delivered NaCl (page 83). Hackett et al teach that a *Salmonella*

stanley strain a DTH (cellular) response of 3.7 fold over the control was seen in immunized mice. Thus, Hackett teach compositions comprising fla- strains (stains that do not produce flagellin, therefore they are not capable of inducing an immune response to at least one antigenic determinant of flagellin). Hackett et al do not teach the use of adjuvant, However, Cox et al teach adjuvants have been used to improve vaccine efficacy since the 1920s. One of ordinary skill in the art would be motivated to add an adjuvant to the compositions of Hackett et al because Cox et al teach that adjuvants improve vaccine efficacy. Thus, the combination of references teach the claimed invention.

In view of all of the above this rejection is maintained.

New Grounds of Rejection

Claim Objection

10. Claim 36 is objected to for the following informality: "mutatedbacteria" should be changed to "mutated bacteria". Correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

11. Claims 21 and 36 are rejected under 35 USC 112 second paragraph for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 21 and 36 recites the limitation "...*S. typhimurium* strain STMP mutated bacterium...". It is unclear as which bacterium is referring. Is Applicant

referring to STM2000 (page 16 of instant specification) or STM2001 (pages 16-17 of instant specification and strain deposited with Centraalbureau voor Schimmelcultures, Baarn, The Netherlands under accession number CBS 108955). Correction or clarification is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

12. Claims 7, 20, 38 and 40 are rejected under 35 U.S.C. 102(b) as anticipated by Hackett et al (*The Journal of infectious Diseases, Vol. 157, No.1, January 1988).*

Claims 7, 20, 38 and 40 are drawn to immunogenic compositions for allowing the marking of an exposure to a subject to wild-type *Salmonella* said immunogenic composition comprising an immunologically effective amount of a live mutated bacteria and pharmaceutically acceptable carrier; wherein said live mutated bacteria are Salmonella enterica that in their wild-type form carried flagella having at least one antigenic determinant and wherein after mutation said live mutated bacteria are not capable of inducing an immune response to the at least one antigenic determinant of flagellin so as to allow marking of an exposure of the subject to the wild-type *Salmonella* in the subject to which its is administered.

Hackett et al teach vaccine composition comprising flagella negative (fla-) strains of live *Salmonella* bacteria (see the Abstract). Hackett et al teach that were constructed

by mutating the fla gene (pages 78-79). Hackett et al teach that the vaccine composition were delivered NaCl (page 82). Hackett et al teach that a *Salmonella* stanley strain a DTH (cellular) response of 3.7 fold over the control was seen in immunized mice. Thus, Hackett teach compositions comprising fla- strains (stains that do not produce flagellin, therefore they are not capable of inducing an immune response to at least one antigenic determinant of flagellin). Hackett et al anticipate the claimed invention.

Status of Claims

13. No claims allowed.

Conclusion

14. Any inquiry of the general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (703) 308–0196.

Papers relating to this application may be submitted to Technology Center 1600, Group 1640 by facsimile transmission. The faxing of such papers must conform with the notice published in the Office Gazette, 1096 OG 30 (November 15, 1989). Should applicant wish to FAX a response, the current FAX number for the Group 1600 is (703) 872-9306.

Any inquiry concerning this communication from the examiner should be directed to Vanessa L. Ford, whose telephone number is (571) 272-0857. The examiner can normally be reached on Monday – Friday from 9:00 AM to 6:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew, can be reached at (571) 272-0787.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov./>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Vanessa L. Ford
Biotechnology Patent Examiner
July 5, 2007

JEFFREY SIEW
SUPERVISORY PATENT EXAMINER